[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Single-Chain Antibodies Directed to Norovirus GI.1 and GII.4 and Their Use

Description of Technology:

Vaccines and therapies to prevent and treat Norovirus infections are not available, despite the worldwide prevalence of Norovirus infections. Outbreaks of human gastroenteritis attributable to Norovirus commonly occur in group settings, such as hospitals, nursing homes, schools, dormitories, cruise ships and military barracks. This application claims isolated VHH monoclonal antibodies that specifically bind to a Norovirus polypeptide. Llama-derived single chain antibody fragments (also called VHH) are small, recombinant monoclonal antibodies of 15 kDa ("nanobodies") with several advantages over conventional antibodies. The antibodies that were derived from llamas showed strong neutralizing activity against Norovirus in *in vitro* assays. These nanobodies may have application as immunoprophylaxis to protect individuals from infections or as a possible treatment for infected individuals, or can be used to develop a diagnostic for detection of norovirus infections, and may be potentially utilized in vaccine research.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Therapeutics
- Diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- Potent neutralizing activity
- Potential cross-reactivity
- Low-cost therapeutics/immunoprophylaxis

Development Stage:

- In vivo data assessment (animal)

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Publications: Garaicoechea L. et al., "Llama nanoantibodies with therapeutic potential against human norovirus diarrhea," PLoS One. 2015 Aug 12;10(8):e0133665. doi:10.1371/journal.pone.0133665. eCollection 2015. [PMID 26267898].

Intellectual Property: HHS Reference No. E-136-2013/0—U.S. Provisional Application No. 61/821,354, filed May 9, 2013; PCT Application No. PCT/US2014/037520, filed May 9, 2014; European Application No. 14727696.8, filed May 9, 2014 (pending); U.S. Application No. 14/889,774, filed November 6, 2015 (pending); and Argentine Application No. 20140101882, filed May 9, 2014 (pending).

Licensing Contact: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a therapeutic, diagnostic or vaccine for Norovirus infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Dated: February 8, 2017

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Suzanne Frisbie,

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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